

§ 201.105(c) of this chapter, provided that they meet the conditions prescribed in this paragraph. Preparations that are not in dosage unit form (for example, solutions) will be regarded as meeting the conditions with respect to the maximum quantity of drug per dosage unit if they are prepared in a manner that enables accurate and ready administration of a quantity of drug not in excess of the stated maximum per dosage unit:

*Atropine sulfate.* As an injectable for cattle, goats, horses, pigs, and sheep, not in excess of 15 milligrams per dosage unit; as an injectable for cats and dogs, not in excess of 0.6 milligram per dosage unit.

*Barbital sodium.* For oral use in cats and dogs, not in excess of 300 milligrams per dosage unit.

*Epinephrine injection. 1:1,000.* For cats, dogs, cattle, goats, horses, pigs, and sheep (except as provided in § 500.65).

*Morphine sulfate.* As an injectable for dogs, not in excess of 15 milligrams per dosage unit.

*Pentobarbital sodium.* For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

*Phenobarbital sodium.* For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

*Procaine hydrochloride injection.* Containing not in excess of 2 percent procaine hydrochloride, with or without epinephrine up to a concentration of 1:50,000. For use in cats, dogs, cattle, goats, horses, pigs, and sheep.

*Thyroid.* For oral use in dogs, not in excess of 60 milligrams per dosage unit.

#### Subpart D—Requirements for Specific Animal Drugs

##### § 500.65 Epinephrine injection 1:1,000 in 10-milliliter containers for emergency treatment of anaphylactoid shock in cattle, horses, sheep, and swine.

(a) Anaphylactoid reactions in cattle, horses, sheep, and swine occur occasionally from the injection of antibiotics, bacterins, and vaccines. Adequate directions for use of these antibiotics, bacterins, and vaccines can generally be written for use by the laity and thus are available to livestock producers. Epinephrine injection is effective for the treatment of anaphylactoid reactions in animals and would be of value in saving lives of animals if it were readily available at the time of administration of the causative

agents. In connection with this problem the Food and Drug Administration has obtained the views of the Advisory Committee on Veterinary Medicine, and other experts, and has concluded that adequate directions for over-the-counter sale of epinephrine injection 1:1,000 can be prepared.

(b) In view of the above, the Commissioner of Food and Drugs has concluded that it is in the public interest to make epinephrine injection 1:1,000 available for sale without a prescription provided that it is packaged in vials not exceeding 10 milliliters and its label bears, in addition to other required information, the following statements in a prominent and conspicuous manner: "For emergency use only in treating anaphylactoid shock. Usual Dosage: Cattle, horses, sheep, and swine—1 cubic centimeter per 100 pounds of body weight. Inject subcutaneously".

(c) The labeling must also bear a description of the symptoms of anaphylactoid shock including glassy eyes, increased salivation, grinding of the teeth, rapid breathing, muscular tremors, staggering gait, and collapse with death following. These symptoms may appear shortly after injection of a bacterin, vaccine, or antibiotic.

#### Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

SOURCE: 52 FR 49586, Dec. 31, 1987, unless otherwise noted.

##### § 500.80 Scope of this subpart.

(a) The Federal Food, Drug, and Cosmetic Act requires that sponsored compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for consumption by people. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by people or animals unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs) that no residue of that compound will be found in the food produced from those animals

under conditions of use reasonably certain to be followed in practice. This subpart identifies the steps a sponsor of a compound shall follow to secure the approval of the compound. FDA guidance documents contain the procedures and protocols FDA recommends for the implementation of this subpart. These guidance documents are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for these guidance documents should be identified with Docket No. 1983D-0288.

(b) If FDA concludes on the basis of the threshold assessment that a sponsor shall conduct carcinogenicity testing on the sponsored compound, FDA will also determine whether and to what extent the sponsor shall conduct carcinogenicity testing on metabolites of the sponsored compound. The bioassays that a sponsor conducts must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.

(c) If FDA concludes on the basis of the threshold assessment or at a later time during the approval process that the data show that the sponsored compound and its metabolites should not be subject to this subpart, FDA will continue to consider the compound for approval under the general safety provisions of the act for risks other than cancer.

(d) This subpart does not apply to essential nutrients.

[52 FR 49586, Dec. 31, 1987, as amended at 59 FR 14365, Mar. 28, 1994; 62 FR 66983, Dec. 23, 1997; 65 FR 56480, Sept. 19, 2000; 67 FR 78174, Dec. 23, 2002; 68 FR 24879, May 9, 2003; 69 FR 17292, Apr. 2, 2004]

#### § 500.82 Definitions.

(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this subpart.

(b) The following definitions apply to this subpart:

*Act* means the Federal Food, Drug, and Cosmetic Act (sections 201–901, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 301–392)).

*Essential nutrients* means compounds that are found in the tissues of untreated, healthy target animals and

not produced in sufficient quantity to support the animal's growth, development, function, or reproduction, e.g., vitamins, *essential* minerals, *essential* amino acids, and *essential* fatty acids. These compounds must be supplied from external sources.

*FDA* means the Food and Drug Administration.

*Limit of detection (LOD)* means the lowest concentration of analyte that can be confirmed by the approved regulatory method.

*Marker residue* means the residue selected for assay whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to deplete to its  $S_m$ .

*Preslaughter withdrawal period or milk discard time* means the time after cessation of administration of the sponsored compound at which no residue is detectable in the edible product using the approved regulatory method (i.e., the marker residue is below the LOD).

*Regulatory method* means the aggregate of all experimental procedures for measuring and confirming the presence of the marker residue of the sponsored compound in the target tissue of the target animal.

$R_m$  means the concentration of the marker residue in the target tissue when the residue of carcinogenic concern is equal to  $S_m$ .

*Residue* means any compound present in edible tissues of the target animal which results from the use of the sponsored compound, including the sponsored compound, its metabolites, and any other substances formed in or on food because of the sponsored compound's use.

*Residue of carcinogenic concern* means all compounds in the total residue of a demonstrated carcinogen excluding any compounds judged by FDA not to present a carcinogenic risk.

$S_m$  means the concentration of a residue of carcinogenic concern in a specific edible tissue corresponding to no significant increase in the risk of cancer to the human consumer. For the purpose of § 500.84(c)(1), FDA will assume that this  $S_m$  will correspond to the concentration of residue in a specific edible tissue that corresponds to a